

Carol T. Hauser

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Lynchburg, VA 24503-3411

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May 20, 1999

Dockets Managment Branch (HFA-305)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

To Whom It May Concern,

I am extremely distressed to learn that I may not be able to continue to receive my compounded natural progesterone prescription from the Madison Pharmacy located in Madison, WI if the FDA prohibits compounding pharmacies to ship prescriptions across state lines.

In my case, I am unable to take Provera, and when I tried Prometrium on March 23, 1999 a few weeks ago, I developed an allergic reaction to the Prometrium within 20 minutes after taking the first prescribed dose, most likely due to the peanut oil. Adding Benadryl did not solve the underlying reaction to the Prometrium. I had to have progesterone and I needed to stop the Prometrium as quickly as possible to avoid further allergic complications.

I am very thankful that my doctor and I had a choice and a way to obtain the compounded natural progesterone in a safflower oil base to control my problem with Menorrhagia. My doctor was able to fax the prescription, and I was able to make arrangements to have the prescription shipped overnite to me so I could discontinue the Prometrium as quickly as possible to remove the offending allergen in that medication, but still take the natural progesterone. Fortunately, I was able to receive the individual compounding services from the Madison

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Pharmacy which allowed me to continue the prescribed natural progesterone protocol which I desperately needed. Please do not prevent me from obtaining my medically necessary prescription(s).

It is clear and obvious that the local drug store chains in our area such as CVS and Rite-Aid Drugs and/or the large commercial pharmaceutical companies are unable to meet my needs in regards to compounded hormonal prescriptions, nor would they order and/or deliver this type of prescription to me overnite if needed.

I received excellent service from Madison Pharmacy, in WI and feel confident with their history and background and experience of compounding womens' prescriptions for the past twenty years and that they will be able to continue to meet my individual needs for the next 5-10 years as I transition from perimenopause through menopause.

It is critical to me to have the peace of mind to know that I will be able to obtain whatever prescription that my doctor and I find are appropriate for my medical care and well being. **Please do not dismantle a system that is working for thousands of women.** There are millions of baby boom women facing menopause in the coming years and we need to have this service.

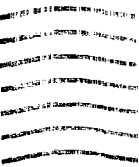
Sincerely,

A handwritten signature in cursive script that reads "Carol T. Hauser".

Carol T. Hauser



M/M Robert Hauser
401 Brookfield Road
Lynchburg, VA 24503



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